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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,764	12/30/2003	Madhav S. Thakur	ORT-0957-USA-DIV	8725
27777	7590	05/03/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			VENKAT, JYOTHSNA A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/748,764

Applicant(s)

THAKUR ET AL.

Examiner

JYOTHSNA A. VENKAT Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-23 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-23 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/17/04 and 6/9/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Receipt is acknowledged of election filed on 2/14/04.

1. Applicant's election with traverse of group I in the reply filed on 2/14/05 is acknowledged. The traversal is on the ground(s) that even though applicants agree with the Examiner's findings that the alleged separate inventions are patentable over each other; there is no serious burden since Groups I and 11 are both classified in class 424, subclass 489. This is not found persuasive because even though the two inventions are in the same class and subclass it is indeed search burden to examine the non-patent literature since both the groups are drawn to distinct method of uses.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 27-36 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 2/14/05.

Claims 15-23 and 26 are pending in the application and the status of the application is as follows:

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 15-23 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of PDR (page 2058 of the 52d edition) and U. S. Patent 5,260,072('072) and 5,133,974 ('974).

The instant application is claiming method of treating convulsions administering pharmaceutical compositions comprising:

1. Core particles containing the active ingredient Topiramate and binder (species is povidone) and diluent which are sugar spheres
2. Taste masking coating which has disintegrant (povidone) and taste masking agent (cellulose acetate)

The PDR teaches topiramate as a drug having bitter taste and the drug useful as an epileptic drug. The PDR does not teach the composition claimed core particles and taste masking coating. However patent '072 teaches rotogranulation and taste masking coatings for the preparation of chewable pharmaceutical tablets using drug, which has the bitter taste along with binder povidone and taste masking coating, which is cellulose acetate. See the abstract, and see col.3, lines 55-65 and see col.4, lines 40-55. The patent teaches lactose as the carrier and teaches that other saccharides can be used. The patent at paragraph bridging cols 4-5 and col.5, lines 3-52 teach coating with cellulose acetate and povidone. Patent '974 is relied for the teaching of sugar

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spheres. Patent '974 teaches pharmaceutical preparations using core having the drug, sugar spheres, binder and coated with film forming agent. The particle size of the core particles is same to that of coated particles. See claim 1 and see col.col.4, lines 1-25, and col.5.


Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions using the process of '072 and substitute topiramate taught by PDR having bitter taste for fomatidine and use sugar spheres in the core particles taught by '974 expecting beneficial effect. One of ordinary skill in the art would be motivated to prepare compositions of '072 and substitute topiramate for fomatidine with the reasonable expectation of success that the pharmaceutical composition exhibit better balance between taste masking, dissolution and rate of bioavailability and adding sugar spheres in the core aids in the diffusion/release of the drug from the formulation. It is a prima facie of obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30: 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K. PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
**Art Unit 1615**

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